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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,224	08/09/2001	Timothy L. MacDonald	00399-12	3575

7590

09/06/2002

John P. Breen
University of Virginia Patent Foundation
1224 West Main Street, Suite 1-110
Charlottesville, VA 22903

EXAMINER

PATEL, SUDHAKER B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/06/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,224

Applicant(s)

Timothy L. Macdonald et al

Examiner

Sudhaker Patel

Art Unit

1624



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 27, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3, 6, 7 6) ☐ Other: _____

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DETAILED ACTION

Applicants' communication paper # 10 dated 6/27/02 is acknowledged.

The claims in this application are the claims 4-29.

I. Restriction/Elections: Applicants have elected invention of Group I as represented by generic Formula of claim 4 wherein R1,R7,R8 are H, Halogen, Haloalkyl or hydroxy; and R3 is hydroxy or -OCONH2 i.e. non-heterocyclic structure.

The restriction/election is considered proper and is made FINAL.

II. Rejections withdrawn: Applicants have amended claims 4-17, canceled claims 1-3, and presented new claims 18-29 to add clarity to the claimed invention. Therefore, rejections made under 35 U.S.C. 112 para second are now withdrawn.

III. Rejections maintained: Rejections made under 35 U.S.C. 112 para one

Applicants' arguments and remarks have been considered but not found persuasive for withdrawal of rejections. Therefore, rejections for claims 4-29 are maintained further for the reasons already stated in earlier Office Action paper.

Additionally, the method of use claim 9 as amended recites :” a method for preventing or limiting tissue damage....., said method comprising the step of administering a composition.....

There's no sufficient supporting evidence and data for preventing or limiting the tissue damage.

Similarly, the new claim 27 recites:” a method for reducing the incidence and severity of epileptic seizure in an individual....” for which the claim lacks supporting evidence.

Following documents provide current state of the art.

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A Review of efficacy and safety for antiepileptic drugs:

Shields clearly states(see PubMed Abstr. 8275978;Epilepsia, 35/2,24-29(1994)) that “Many of these pediatric disorders are notoriously unresponsive to currently available antiepileptic drugs..... No screening program uses an animal model of seizures that begin during development and lead to functional decline”.

Biological activity of carbamate analogues:

Knight et al state(see PubMed Abstr. 9808108; Seizure, 7/5,347-54(1998)) that “ With the resulting mathematical model, the biological activity of carbamate analogues can be predicted with 85-90% accuracy”.

IV. Rejections maintained:

Double Patenting

The obviousness-type double patenting rejections for claims 4-29 are maintained further for the reasons already stated in the earlier Office Action paper# 8, dated 2/25/02. Co-pending U. S. Patent Application Sr. No. 09913075 filed 8/9/01 is still under going preexam processing, and is not available to examiner. The other co-pending application U. S. Sr. No.10023059 filed 12/17/01 for which applicants have provided a copy of claims, is also having duplication of claims. Note, new claim 31 formula and compounds, compositions and method of use claims 41-

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45 overlap with the instant claims wherein R9 = H; R7, R8 = H; R3 = hydroxy or -OCONH2.

Therefore, the double patenting rejections are maintained further.

V. *Information Disclosure Statement*

Examiner appreciated, applicants' efforts to provide the copies of the various articles. Forms PTO-1449 are enclosed herewith after signing the same for applicants' records.

VI. *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709. The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Mukund J. Shah
MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1600



SP/August 30, 2002.